

Utah CTSI Community & Academic Partnership Pilot (CAPP) Program



Required Letter of Intent (LOI) Due:
September 15, 2023 by 5pm MST

Invited Full Application Due:
December 18, 2023 by 5pm MST

The National Center for Advancing Translational Sciences’ (NCATS) Clinical & Translational Science Award (CTSA) program seeks to develop and implement innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities.

The Utah Clinical & Translational Science Institute (CTSI)’s mission is to foster the highest quality clinical and translational science that supports increased efficiency and effectiveness of research, and ultimately improves the health of our population—reducing health disparities and increasing equity.

Both NCATS and the CTSI’s objectives cannot be fully realized without close collaboration with the communities they serve.

Application Focus

Leveraging CTSA and institutional funding, the Utah CTSI’s Community and Academic Partnership Pilot (CAPP) program will support collaborations between community organizations located in Utah and adjacent states, and CTSI-affiliated academic partners that address at least one of the following focal areas:

Address barriers to conducting clinical & translational research	<p>Projects that develop or evaluate an innovative methodology, technology, tool, resource, or training paradigm that seeks to address an identified barrier to conducting clinical and translational research. The new innovation should be broadly generalizable to many research projects.</p> <p>Example barriers include (but are not limited to): clinical trial outcomes that are selected without patient involvement and thus mean little to patients or their communities, study designs that are developed without consulting patient representatives and thus are not feasible for potential participants or do not address barriers to participation, participant recruitment plans that are developed without consulting representatives of the target population(s) and thus do not reach appropriate individuals, lack of a clear informed consent process that can be understood by all potential participants, lack of broad inclusiveness in research studies and clinical trials, lack of disseminating research findings broadly in ways that are most appropriate for participants and communities, etc.</p>
Advance human health	<p>Projects that seek to translate observations and/or data collected in the community, clinic or laboratory into interventions that improve the health of individuals and communities.</p> <p>Example interventions include (but are not limited to): attitude or behavioral changes, preventive measures, diagnostics, treatments, or medical procedures.</p>

Understand and reduce health disparities	<p>Projects that seek to understand and alleviate inequities in health and health care, especially in racial and ethnic minority groups, rural populations, and groups who experience social and economic disadvantages and barriers to health or health care</p> <p>Example projects include: documenting and addressing significant health differences in disease incidence and prevalence, and/or morbidity, mortality, or survival rates, or health care delivery and uptake; understanding social determinants of health and how they contribute to disparities in health care and health outcomes, and addressing them; developing or testing approaches or interventions to reduce inequities and increase equity in health care delivery or health outcomes.</p>
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The CAPP program requires close and equitable collaboration between the community and academic partners. Each pilot must be led by a PI from the community organization and a PI from the CTSI-affiliated academic partners. Both must be involved throughout the development and execution of the proposed project.

For funded projects, the project team will receive mentoring and support from the CTSI Community Collaboration and Engagement Team (CCET) co-directors and staff with the goal of supporting all project partners in building their capacity for community-based participatory research.

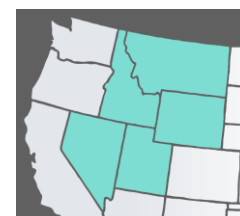
It is expected that the research supported by each of these pilot awards will result in one or more publications and/or presentations, and will collect data that will be used to apply for funding from NIH or other funders to expand and continue the projects.

Key Information

Posted Date	July 31, 2022
CAPP FOA Application Presentation	Wednesday, August 16, 2023 from 12-1pm MST <i>All faculty members-senior as well as junior investigators-are invited to attend along with community leaders/partners. This event is targeted to those applying for the CAPP pilot.</i>
Letter of Intent (LOI) Due Date	Friday, September 15, 2023 by 5:00 pm MST
Invitation to submit full application	November 3, 2023
Full Application preparation with Advisor and Design Consultations	November 3 – December 18, 2023
Application Due Date	Monday, December 18, 2023 by 5:00 pm MST
Notice of Intent to Fund	February 1, 2024
Just-in-Time (JIT) Period	February 1 – April 1, 2024
Anticipated Start Date	April 1, 2024 * (pending JIT fulfilment)
Announcement Expiration Date	September 16, 2023
Award Budget	Up to \$60,000 <i>Please note: All funds not spent by the end date of the CTSA CAPP Award will be returned. Extensions are not allowed.</i>
Questions?	utahctsi_pilots@hsc.utah.edu & allow 2-3 business days for replies

CAPP Program Eligibility Criteria

- Collaboration between the following is required:
 - Leader(s) of a community organization located in Utah or surrounding states as highlighted in the figure to the right



- Researcher(s) holding a faculty or equivalent appointment at the University of Utah or a Utah CTSI partner organization (Utah Department of Health, Veterans Affairs Salt Lake City Health Care System, or Intermountain Healthcare). Both tenure-line faculty and career-line faculty are eligible to apply.
- Successful projects will exemplify NCATS's and the Utah CTSI's missions as described above.
- Applicants who have significant start-up funds, cash reserves, or are seeking gap funding to bridge support between external grants or contracts are not eligible.
- The proposed project should not be funded by any other mechanism/research initiative at the time of submission.

Application Timeline and Process

The CAPP application and review process is as follows:

1. **Letter of Intent (LOI):** Applicants will submit a required LOI due September 15, 2023, containing standardized components outlined below. LOIs will be reviewed by a panel of community and academic reviewers for scientific merit, significance, innovation, alignment to this FOA, and strength of the community-academic partnership. A subset of LOIs will be invited on November 3, 2023 to submit a full application. A summary of strengths, topics that need additional details, and any weaknesses that should be addressed in the full application will be shared.
2. **Assistance in the Preparation of Invited Full Applications:** The following support will be available to enhance the preparation of invited full applications, with particular emphasis on enhancing the community-academic partnership and the identification of measurable outcomes.
 - **Advisors:** Applicants will be assigned an Advisor from a pool of experienced faculty. The Advisor will meet with the applicants at least twice over the preparation period to review the application, suggest improvements, and help define achievable metrics for the one-year project period.
 - **Community Engagement Consultation(s):** Applicants will meet at least once with one of the CTSI Community Collaboration and Engagement Team (CCET) co-directors; they also may meet with CCET staff, if appropriate for their proposed study. CCET will provide consultation on:
 - Community-academic collaboration throughout the research life cycle, such as:
 - Designing collaborative community-academic research
 - Designing community-engaged research studies
 - Planning for participant recruitment and retention
 - Developing community-appropriate informed consent materials and processes
 - Engaging in collaborative community-academic data analysis and interpretation
 - Sharing research findings with community members
 - CCET Services that may be included as part of proposals
 - Engagement Sessions (focus groups and interviews)
 - Community Advisory Boards
 - Community Dialogues sessions
 - Consulting community stakeholders who are members of the Community Faces of Utah collaborative
 - **Design Consultations:** Applicants are also encouraged to consult with experts from the other Utah CTSI Cores and Services who will make their time and expertise available for this purpose during the application preparation period. These design consultations will help applicants consider and implement modifications that address weakness in their application (e.g. statistics, study design). Services can be requested directly at ctsi.utah.edu or can be facilitated by the CTSI's Pilot Program Manager. CTSI Cores and Services include:

- Community Collaboration & Engagement Team
 - Translational Research: Implementation, Analysis & Design Team
 - Study Design & Biostatistics
 - Cancer Biostatistics
 - Health Economics
 - Qualitative Services
 - Survey Design & Measurement
 - Systematic Review
 - Clinical Research Unit (space and nursing services for clinical research)
 - Biomedical Informatics Core
 - Cellular & Translational Research Core
 - Clinical Research Support Office
3. **Invited Full Applications:** The invited full application will be due December 18, 2023. The application will include a description of how the design consultations enhanced the application and, if IRB approval will be needed for the study, a draft of the research study protocol that would be submitted to the University of Utah Institutional Review Board (IRB). For each application, reviewers will provide an NIH-style scientific content review, including impact score and an Overall Impact/Merit paragraph that summarizes the factors informing the Overall Impact score. A subset of full applications will be recommended for funding, and notifications will be sent by February 1, 2024.
4. **Just-in-Time (JIT) Period and Notice of Award:** Applications recommended for funding that include human or animal research will receive a Just-in-Time request including submission of:
- Official IRB determination of human subjects or non-human subjects research.
 - IRB approval or congruency letter
 - Current [Collaborative IRB Training Initiative \(CITI\)](#) and Good Clinical Practice (GCP) training for the PIs and other individuals who will interact with research study participants
 - Community partners may complete either the in-person CIRTification training offered by the IRB or the [online version](#)
 - Vertebrate Animal Section Document* and IACUC approval
 - i. * <https://olaw.nih.gov/guidance/vertebrate-animal-section.htm>

CAPP Submission Instructions

The Utah CTSI CAPP program **requires** all applicants to adhere to the following instructions when preparing their Letter of Intent (LOI) and full application. Failure to adhere to instructions may result in administrative rejection of the application.

- **University of Utah Internal Process:** The Pilot Program Application **does not** require prior consideration by the University of Utah Office of Sponsored Projects (OSP). **An eProposal should not be created for this application.**
- **Font:** Arial, 11 point, not condensed
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm)
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions
- **Footer:** Label each page in the footer with the names of both PIs and the name of the document. Align the first letter of this text with the left margin. *No Headers
 - i. Example: Names of both PIs, Name of document; “Jane Doe & John Doe_CoverPage”
 - ii. Excluded from Biosketch(s), Other Support, IRB/IACUC draft application & budget excel file

- *Internet URLs:* Other than the NIH Biographical Sketches or Bibliography & References Cited documents, URLs directing reviewers to websites that contain additional information about the proposed research are not allowed.
- *Organization:* The content of the LOI and full application should be structured as outlined in the instructions. The start of each numbered section/component should be on a new page and clearly labeled with the section title.
- *Tables, Graphs, Figures, etc.:* All tables, graphs, figures, diagrams, and charts must be included within the overall page limit. If included, figures and tables may have a font size as small as 8 points.
- *Notice of Proprietary Information:* Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, either financial or commercial, or that is confidential or privileged, please identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: “*The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released except for purposes of review and evaluation.*”

Letter of Intent (LOI) Instructions

A Joint Letter of Intent (LOI) is **required** and must be submitted by **September 15, 2023 by 5:00 pm MST.** The Contact Principal Investigator will submit the LOI via a Redcap survey [link](#).

- *The REDCap survey link will be active September 1-15, 2023 until 5.01 pm MST.*

Required 5-page maximum* LOI Components:

1. Cover Page (1-page limit)
 - Project Title
 - Community Organization Principal Investigator & Academic Principal Investigator (PIs) – name, title, organization (department, if relevant), contact information (email address, best phone number, mail address)
 - Key Personnel from both the community and academic organizations – name, title, organization (department, if relevant), contact information (email address, best phone number, mail address), project role
 - Note: Key Personnel are individuals who would be important in carrying out the proposed project, but who are not co-Principal Investigators
 - Brief description of the composition and qualifications of the project team
2. Community-Academic Partnership description (1-page limit)
 - Briefly describe the history of your partnership
 - If this is a recently formed partnership, describe how you met and decided to work together
 - Briefly describe the ways both partners have been involved in developing the proposed project plan
 - For the proposed project, describe the responsibilities the community partner will have and the responsibilities the academic partner will have
 - Describe the ways this project will be beneficial for both the community and academic partners
3. Research Strategy (3-page limit)
 - Specific Aims
 - These are the project goals
 - Significance and Rationale
 - Include a description of the project, its potential benefits, and ways in which it is innovative, as well as the importance of the knowledge to be gained.
 - Methods

- Include a brief description of the proposed methods
 - Expected Outcomes and Metrics for Success
- 4. Bibliography and Literature Cited excluded from 5-page maximum
- 5. A Biosketch for each of the co-Principal Investigators (Community and Academic PIs), following NIH instructions for submission on or after 01/2022 (bios are limited to *5-pages each; they are not included in the 5 page-maximum for the LOI)

Full Application Instructions

Full application components are due by **December 18, 2023 by 5:00 pm MST.**

- *Principal Investigators will submit within the REDCap survey link provided in their invitation to submit a full application, emailed on November 3, 2023.*

Required 9-page maximum* full application:

1. Cover Page (1-page limit)
 - Project Title
 - Co-Principal Investigators & Key Personnel
 - Summary/Abstract (30 lines)
 - Lay Summary (250 words)
 - A few sentences summarizing the project and its goals and potential impact, written in language that is understandable to a general audience.
2. Description of changes/improvements that were made to the full proposal (after the LOI) following advisor consultations and design sessions (1-page limit)
 - Respond to the issues and criticisms raised in the LOI reviewers' comments
3. Community-Academic Partnership Plan (1-page limit)
 - Describe the ways both partners have been involved in developing the proposed plan.
 - Describe the responsibilities the community partner will have and the responsibilities the academic partner will have for the proposed project.
 - Describe the ways this project will be beneficial for both the community and academic partners.
4. Research Plan (5-page limit)

Organize the Research Plan in the order specified below, using the guidelines provided:

 - Start each section with the appropriate section heading: Specific Aims, Background and Significance, Innovation, and Research Design and Methods.
 - Provide the full reference number for each journal article or other source in the Bibliography and Literature Cited section (which is not included in the page limits).
 - a) Specific Aims

In this section, state concisely the goals of the proposed project. Focus your specific aims to ones that can be reasonably achieved, given the 12-month timeframe and available funding. When writing Specific Aims, consider the following:

 - What is your overall goal?
 - What do you propose to do in this project?
 - What outcomes do you aim to achieve?
 - b) Background and Significance

A sound research project should demonstrate the context of the proposed work within the team's prior work and/or the work of others.

 - Identify the need/barrier the project will address.
 - Explain the importance of the need/barrier that the proposed project addresses, both to the community and to science.
 - Describe the scientific basis for the proposed project, including analysis of the strengths and weaknesses of current approaches (if any) to addressing the

community-identified need, and published research or preliminary data that support your plan for addressing this need.

- Explain how the proposed project will improve the conduct of translational research, improve the health of community members, advance scientific knowledge, and/or improve clinical practice, if the proposed aims are achieved.

c) Innovation

- Describe what is new and innovative about your proposed project.
- In what ways will your approach or the need you are addressing be different from current programs or practices?
- Why do you think (hypothesize) that your approach/program will be more effective than current approaches/programs?

d) Research Design and Methods

- Describe any prior research/work (Preliminary Studies) by your team that have provided information or data relevant to your proposed project. (preliminary data are not required)
- Describe your plan for achieving the specific aims of the project.
- Describe the research design and methods you will use and how they will result in robust and unbiased results.
- Describe how the research data will be collected, analyzed, and interpreted and ways each partner will be involved in the analysis.
- Describe any potential problems in carrying out your research plan and how you plan to address them if they arise.
- Describe how results or findings from the research will be disseminated to the community and ways in which each partner will be involved in dissemination.
- Briefly describe any manuscripts you expect to come out of your proposed project, the journal(s) to which you plan to submit them, and the ways in which each partner will be involved in preparing the manuscripts.
- Include a Timeline that lists each major task for the proposed research, who will be responsible for carrying it out, and the months when you anticipate carrying it out.

5. Bibliography and Literature Cited *excluded from 9-page maximum, no page limit

- Provide a bibliography of any references cited in the Research Plan.
- Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal or book title, volume number, page numbers, and year of publication. Provide any references cited in this application utilizing the [American Medical Association Style JAMA](#).

6. Plan to Obtain Additional Funding (1-page limit)

- Identify the specific funding opportunity(s) to which you plan to apply, using the pilot data obtained from the proposed project; include funding announcement number(s) and name(s).
- Describe the ways in which the pilot project data will support and strengthen these grant proposals.
- Include a timeline for grant submission, including the target date for submitting your application.

7. PDF of entire completed draft IRB/IACUC application ****don't submit yet, leave in 'in progress' state!****

- **Don't submit to IRB/IACUC until notified by CTSI** (process will commence after award notification/JIT period).
- Please note: the IRB/IACUC application title must match exactly the title of the CTSI pilot application
- If your proposed pilot is an ancillary study to an existing IRB/IACUC approval, a congruency letter will be required during the JIT period

- If your proposed pilot will involve human specimens and/or data, but is not considered human subjects research, an official IRB determination of non-human subjects' research will be required during the JIT period.
8. NIH Biosketches for:
 - Each of the Principle Investigators (Community and Academic PIs)*
 - Key Personnel (academic and community)*
 9. Letter(s) of Support (optional)
 10. Authentication of Key Biological and/or Chemical Resources (*if applicable*)
 11. Budget (use required template, found in REDCap survey)
 - Requested budgets should be based on the proposed project needs.
 - No proposal may exceed a request of \$60,000.
 - Include an itemized table for the budget, listing categories and costs separately for the community organization and the CTSI-affiliated academic researcher in accordance with the budget guidelines listed in this FOA. For example:
 - Salaries and/or Wages
 - List each named person on a separate line
 - List each type of person who is not specifically named, on a separate line
 - Show salary/wage and benefits for each person or type of person
 - Materials and Supplies
 - Research Participant Support
 - Consultants (such as for CTSI services)
 - Travel
 - Registration fee(s) and/or travel to present the research at professional conferences/meetings
 - Can only be included for community partners, not academic partners
 12. Budget Justification (maximum of 3 pages)
 - Travel for community partners to present at professional conferences/meetings must name the conference/meeting, list who will attend, and provide a detailed budget for the conference.
 - Provide a detailed justification for each expense listed in the budget.

* NIH Biosketch required to follow the new instructions for submission on or after 01/2022, found here: <https://grants.nih.gov/grants/forms/biosketch.htm> (5-page limit, *excluded from 9-page maximum)

Budget Instructions

Due to the collaborative nature of this proposal, budget guidelines are listed for the community partner and the academic partner separately as regulations apply differently. There is not a set funding amount that must go to each category, however please ensure funds are budgeted and spent in accordance with the below instructions and federal regulations. It is recommended that you discuss potential budget expenses with the Program Contact on this announcement if you have questions. Awards are not transferable to any other organization.

Community Partner Budget Guidelines

1. Typical expenses may include:
 - Incentives for research participants
 - Including food and beverage, if justified; additional approval from CTSI required
 - Payments or other incentives for Community Health Workers or other individuals to recruit participants, carry out a program, and/or collect data
 - Including food and beverage, if justified; additional approval from CTSI required
 - Payment for community leaders/members for work performed outside of normal job scope when necessary for the completion of the project
 - Supplies needed to conduct the research project

- Charges for CTSI services such as engagement sessions, survey design, or statistical analysis
 - Travel to present or co-present project findings at professional conferences
 - Dissemination events with research participants and/or community members
 - Including food and beverage, if justified; additional approval from CTSI required
2. The following costs are not covered by these awards:
- Alcoholic Beverages

CTSI-Affiliated Academic Budget Guidelines

1. Typical expenses include:
- Incentives for research participants
 - Technical supplies needed to conduct the research project
 - Charges for CTSI services such as engagement sessions, survey design, or statistical analysis
2. The following costs are not covered by these awards:
- Faculty salaries (including adjunct & visiting)
 - Post-doctoral salaries for those already listed as a trainee on a T grant
 - Graduate student stipends or tuition (stipends are from grants or other awards)
 - Meals or hospitality (i.e., no food, beverages, or alcohol)
 - Travel that is not directly related to the conduct of research (including travel to present findings)
 - Other items typically supported by indirect costs
 - Monetary incentives for health care clinics to participate in research

Letter of Intent and Full Application Review Criteria

All applications are evaluated for scientific and technical merit. Both Letters of Intent and Full Applications will be reviewed by a panel that includes both community leaders/members and academic researchers who have experience in conducting community-engaged research. LOIs and proposals will be reviewed for scientific merit and translational science potential using the NIH Review Criteria listed below.

1. **Overall Impact:** Reviewers will assess the likelihood for the project to exert a sustained, powerful influence on the research field(s) and community(s) involved, in consideration of the following scored review criteria, and additional review criteria will be assigned. An application does not need to be strong in all categories to be judged likely to have major scientific impact.
2. **Innovation:** Does the application challenge and seek to shift current research, clinical practice and/or community-engaged research paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, interventions, or communities? How do these innovations overcome barriers to the performance of translational research? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
3. **Significance:** Does the project address an important problem or a critical barrier to progress in the field and to the performance of translational research or community engagement? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, clinical practice, community-engaged research and/or community-engaged research capacity be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
4. **Approach:** To what extent does the proposed project exemplify collaborative, community-academic research in which both community and academic researchers are full partners? In what ways are both

partners equitably engaged in the research study? Are the overall strategy, methodology, and analyses sections well-reasoned and appropriate to accomplish the specific aims of the project? Has the research team presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are plans for disseminating study findings to community members/research participants clearly outlined? Are potential problems, alternative strategies, and benchmarks for success presented?

5. **Environment:** Will the community and academic environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the community(s) that are involved, scientific environment, or collaborative arrangements?
6. **Investigators:** Are the co-Principle Investigators, and other team members well suited to the project? Preference will be given to early career-investigators, investigators who have not received CTSI pilot funding in the last three years, and investigators pursuing a new research direction.
7. **Probability that this project will lead to extramural funding:** Is the plan for future extramural funding clear and realistic? Are there opportunities or barriers that may increase or decrease the likelihood for future funding?